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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,522	08/25/2003	Daniel C. Sigg	P0011031.00	2282

27581 7590 12/23/2009
MEDTRONIC, INC.
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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

MAIL DATE	DELIVERY MODE
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12/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/647,522	Applicant(s) SIGG ET AL.	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/01/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8,10,12-17 and 43-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,10,12-17 and 43-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/01/2009 has been entered.

Acknowledgements

The Examiner acknowledges the reply filed 10/01/2009 in which claims no claims were amended. Currently claims 1-6, 8, 10, 12-17 and 43-47 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 10, 15, 17, 43-44 and 46-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Vachon et al. (USPN5,833,715). Vachon et al. discloses an implantable lead with therapeutic drug delivery system.

Regarding claims 1-6, 8, 10, 15, 17, 43-44 and 46-47, Vachon et al. discloses a catheter (Figures 8-9) comprising: a catheter body (124) that defines an inner

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lumen(near 56); a retractable/extendable probe (assembly near 186) within the inner lumen that delivers fluid (within 192) to a cardiac tissue site of a patient (col 9, ln 1-20) and is directed by the catheter (124); a seal (96, 188, 194, element attached to 184, piston type member) within the inner lumen and located at a distal end of the catheter body (section near 188); a single point electrode (82) located on the catheter body (connected to 110 and 120, which are located on 124) at a distal end of the catheter body and coupled to the catheter and capable of detect contact between the catheter and the tissue site (col 9, ln 1-40); and an electrical stimulus (through electrical interconnect, 184) to the tissue site is delivered through the single point electrode and the probe (col 9), wherein the probe includes a distal tip formed of an electrically conductive material with two exit ports (202, 204, 206) arranged longitudinally to allow fluid to exit the probe that act as pressure responsive valves (Figure 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 12-14, 16 and 45 are rejected under 35 U.S.C 103(a) as being unpatentable over Vachon et al. (USPN5,833,715) in view of Epstein et al. (USPN6,835,193). Vachon et al. meets the claim limitations as described above except for the supply attachments and delivery of specific macromolecules such as DNA, RNA, etc.

However, Epstein et al. teaches a device and method for controlled depth injections.

Regarding claims 12-14, 16 and 45, Epstein et al. discloses a catheter comprising a catheter body (2) with electrical and fluid attachments (38, 22, 34, 46), the catheter defining an inner lumen (near 16); a probe (14) with a needle tip within the inner lumen that delivers fluid (from 400) to a tissue site of a patient; and at least one electrode (35) coupled to the catheter to detect contact between the catheter and the tissue site. The catheter body (2) is capable of guiding the probe (14) to a tissue site with the probe being retractable and extendable (Figures 3-4) through a distal port (10) to deliver multiple therapeutic macromolecule compounds such as DNA (cols 2 and 17) (Figures 1-6).

At the time of the invention, it would have been obvious to add the therapeutic agents and supply attachments of Epstein et al. to the system of Vachon et al. in order to aid in further tissue treatment and provide a continuous material supply. The references are analogous in the art and with the instant invention; therefore, a

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combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Epstein et al. (cols 1-2).

Response to Arguments

Applicant's arguments filed 10/01/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Vachon et al. (USPN5,833,715) reference does not meet the claimed limitations.

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that the Vachon et al. (USPN5,833,715) reference discloses the claimed invention. The Examiner asserts that the electrode (82) is located on the catheter body by its connection to sheaths 110, 120 which are directly attached to the catheter body (124). Further the Examiner asserts that the electrode (82) is disclosed of being capable of detecting contact with the body and delivering an electrical stimulus (col 9, ln 1-40).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

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The Examiner suggests further clarification of the seal element and complimentary structure with the probe element to be submitted in and after final response.

Conclusion

This is a request for continued examination (filed 10/01/2009) of applicant's earlier Application No. 10/647522. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case.

See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12/17/20009

/Christopher D Koharski/

Examiner, Art Unit 3763

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/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763